The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
Division of Health Professions Licensure

Board of Registration in Pharmacy
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Boston, MA 02114
(800) 414-0168
http://www.mass.gov/dph/boards/pharmacy

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PHARMACY STERILE COMPOUNDING REPORTING FORM
November and December 2012

All Massachusetts pharmacies that are licensed by the Massachusetts Board of Registration in Pharmacy ("Board") and engage in compounding of sterile products are required to complete and submit a Sterile Compounding Reporting Form every six months. This reporting process is designed to ensure that all pharmacies licensed by the Board that perform **sterile compounding** are in compliance with all state and federal laws and regulations, including in particular the United States Pharmacopeia (USP) General Chapter 797 Pharmaceutical Compounding – Sterile Preparations. The form shall be submitted by January 15 and July 15 of each year, with the first six-month report due on July 15, 2013 for the period January – June, 2013.

Massachusetts pharmacies that do **not** engage in **sterile compounding** consistent with USP General Chapter 797 are **NOT** required to submit this form to the Board. Hospital pharmacies are not required to submit this form.

In addition, all Massachusetts sterile compounding pharmacies are required to complete and submit the attached Sterile Compounding Reporting Form for the months of November and December, 2012. Reports must be received by the Board on or before April 26, 2013.

The FAILURE of any Massachusetts pharmacy that performs sterile compounding to provide the requested information to the Board by the January and/or July deadlines will be grounds for discipline under 247 CMR 10.03(q).

Any Massachusetts pharmacy that performs sterile compounding that does NOT provide the requested information to the Board by the required date is NOT authorized to engage in sterile compounding and must IMMEDIATELY CEASE preparing and dispensing all sterile products.

Please direct any questions regarding this reporting form to
pharmacy.admin@massmail.state.ma.us

STERILE COMPOUNDING REPORTING FORM
November and December, 2012

Name of Massachusetts Pharmacy _____

Street Address _____

City/Town _____ Zip Code _____

Tel. No. _____ Fax No. _____

E-mail _____

MA Drug Store Permit Numbers:

Drug Store (DS No.) _____ Exp. Date _____

Controlled Substance (CS No.) _____ Exp. Date _____

Certificate of Fitness (CF No.) _____ Exp. Date _____

List any other registrations below related to the Massachusetts Pharmacy (e.g., manufacturer, wholesale distributor):
DEA Registration No. _____
FDA Registration No. _____ (manufacturer/distributor only)

A. STERILE COMPOUNDING ACTIVITY:

1. Indicate the total number of prescriptions dispensed by month and by USP General Chapter 797 risk-level category (low, medium, high) for the reporting period listed below:

Low-Risk Level Compounding: single volume transfers of not more than 3 sterile dosage forms and not more than 2 entries into a sterile container (e.g., hydrating solutions, irrigations, antibiotics and oncology medications).

Medium-Risk Level Compounding: the compounding process includes complex aseptic manipulations other than single volume transfer (e.g., TPN, cardioplegia solutions, multiple sterile ingredient admixtures).

High-Risk Level Compounding: non-sterile ingredients, including manufactured products not intended for sterile routes of administration, are incorporated or a non-sterile device is employed before terminal sterilization.

November and December 2012				
	Risk Level			
	# Low	# Medium	# High	Total
November volume				
December volume				
Total				

2. Does the Pharmacy dispense Compounded Sterile Preparations (CSPs) to any states and/or jurisdictions outside of Massachusetts? ☐ Yes ☐ No

If Yes, list all states and/or jurisdictions outside of Massachusetts, and status of non-resident licenses:

State/Jurisdiction	**Licensure Status**

3. List all wholesale distributors and any other sources that the Pharmacy receives products from, including chemicals and medications required to produce CSPs (use additional pages if necessary):

4. List all manufacturers that provide the Pharmacy with unsterile Active Pharmaceutical Ingredients (API) (use additional pages if necessary):

B. STAFFING/TRAINING/COMPETENCY EVALUATIONS:

1. List all Pharmacy personnel engaged in preparing CSPs. Attach an organizational chart (management), and additional pages if necessary.

Name	**Title**

_____

_____

_____

_____

_____

_____

2. Do all staff involved in compounding sterile preparations have documented training consistent with USP General Chapter 797? ☐ Yes ☐ No

3. Do all staff involved in compounding sterile preparations undergo a regularly scheduled (at least annually) competency validation? ☐ Yes ☐ No

If Yes, specify frequency: _____

C. QUALITY ASSURANCE:

1. Does the pharmacy have vendor ISO certification within the last six months for:

Hoods? ☐ Yes ☐ No #Hoods_____ #Hoods certified_____

Compounding Aseptic Isolators (CAIs) / Glove box?
☐ Yes ☐ No # CAIs_____ #CAIs certified_____

Ante and buffer areas and any other applicable ISO environments?
☐ Yes ☐ No

2. Regarding sterilization procedures, is the pharmacy in compliance with currently acceptable and achievable sterilization parameters, e.g., temperature, time, humidity, gas concentration, absorbed radiation and biological indicators (BI's) as needed for validation? ☐ Yes ☐ No

3. When was the most recent USP General Chapter 797 Gap Analysis completed?

_____

4. Does the Pharmacy have a data driven Quality Assurance/Performance Improvement Program? ☐ Yes ☐ No

5. If the facility does not use USP General Chapter 797 Beyond-Use Dating, describe your facility's methodology for determining Beyond-Use Dating for CSPs.

_____

_____

_____

D. COMPLIANCE/SANCTIONS:

1. Does the pharmacy only prepare and dispense Compounded Sterile Preparations after receipt of a valid prescription for a single patient? ☐ Yes ☐ No

2. Does the pharmacy maintain a written policy and procedure manual for preparing Compounded Sterile Preparations in conformance with USP General Chapter 797? ☐ Yes ☐ No

3. Is all pharmacy equipment used to prepare Compounded Sterile Preparations stored, used, and maintained in accordance with manufacturer specifications? ☐ Yes ☐ No

4. Were there any disciplinary actions, as defined in 247 CMR 6.15 (including but not limited to revocation, suspension, probation, censure, reprimand, or restriction of the license to operate a pharmacy or practice pharmacy, denial of application for renewal, denial or restriction of privileges or termination from Medicare or Medicaid programs including any adverse actions or fines imposed by a state or federal agency) in the past six months related to the production of sterile compounded products? ☐ Yes ☐ No

If Yes, (a) did the pharmacy report the disciplinary action(s) to the Massachusetts Department of Public Health, Board of Pharmacy (DPH/Board)? ☐ Yes ☐ No

(b) From which program(s) and/or agency or agencies did the pharmacy receive the disciplinary action(s)?

_____

_____

_____

_____

_____

(c) Did the pharmacy provide DPH/Board with a copy of related documents responding to these actions? ☐ Yes ☐ No

5. Was there any adverse change in status of accreditation, as defined in 247 CMR 6.15, including but not limited to withdrawal, discontinuance, termination, revocation, suspension, probation, or warning, in the previous six months? ☐ Yes ☐ No

If Yes, (a) did the pharmacy report this change in status to DPH/Board? ☐ Yes ☐ No

(b) for which accreditation organization(s)?_____

_____

_____

_____

STERILE COMPOUNDING REPORTING FORM
November and December, 2012

Attestation regarding compliance with laws and regulations:

The pharmacy licensee/registrant attests under the pains and penalties of perjury that it is in compliance with all laws and regulations pertinent to sterile compounding, including USP General Chapter 797 - Sterile Preparations. This registrant/licensee only dispenses medication pursuant to a valid prescription as defined in M.G.L. c. 94C §19 for a single patient, regardless of whether the medication is prepared for a Massachusetts or out-of-state patient.

Print Name of Manager of Record (Licensee/Registrant):_____

Title: _____

License Number: _____

Signature of Manager of Record: _____

Date: _____

Please direct any questions regarding this form to pharmacy.admin@massmail.state.ma.us

Mail the completed and signed form and other requested information to the Massachusetts Board of Registration in Pharmacy:

Board of Registration in Pharmacy
ATTN: Compounding Report
239 Causeway Street, 5th floor
Boston, MA 02114

A signed copy may be faxed to 617. 973. 0980 or scanned and emailed to **pharmacy.admin@massmail.state.ma.us** in advance of submission by mail of the signed, original document.